

REMARKS

Please enter this Amendment. Applicant petitioned to revive this application and concurrently filed a CPA on May 24, 2002.

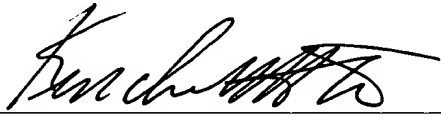
The inventor's Declaration In Support of Petition To Revive withdrew all prior powers of attorney and directed the Patent Office to communicate with the undersigned. A copy of said Declaration is attached as Exhibit A.

The amended specification includes the description from original claims 1-10, whereby the amendment avoids new matter.

Favorable action on the petition and entry of this amendment are respectfully requested.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

By   
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## **APPENDIX**

Starting at page 3, after the heading at line 1, the specification has been amended to include the following text:

The present invention concerns a method for treating Parkinson's disease using an oral dosage formulation comprising an immediate release layer of 10-25 mg of carbidopa and 50-200 mg of levodopa and a sustained release layer of 25-75 mg of carbidopa and 100-400 mg of levodopa whereby, following administration, carbidopa and levodopa are available for rapid and sustained therapeutic action.

An oral dosage formulation in the present method can be further characterized by a sustained release core depot of carbidopa-levodopa overcoated by an immediate release layer of carbidopa-levodopa.

Another aspect of the orally administering the dosage comprises administering a multilayer tablet comprising at least one layer of sustained release carbidopa-levodopa adjacent to at least one layer of immediate release carbidopa-levodopa. If desired, the layers in tablet are separated by an excipient layer.

Another aspect of the invention therefore concerns a pharmaceutical composition in oral dosage form for treating Parkinson's disease, which comprises a combination of an immediate release portion of a combination of carbidopa and levodopa and a sustained release portion of a combination of carbidopa and levodopa and a pharmaceutically acceptable vehicle. The composition is effective in treating Parkinson's disease. The dosage form is such that carbidopa and levodopa are available for immediate and sustained therapeutic action upon administration. The pharmaceutical composition can be in a dosage form that comprises a sustained release core portion of carbidopa and levodopa overcoated by an immediate release layer of carbidopa and levodopa. The pharmaceutical composition can also be in a dosage form that comprises a multilayer tablet which comprises at least one layer of sustained release carbidopa-levodopa adjacent to at least one layer of immediate release carbidopa-levodopa.

In the pharmaceutical composition, in dosage form, an immediate release portion comprises about 10-25 mg of carbidopa and 50-200 mg of levodopa and a sustained release portion comprises about 25-75 mg of carbidopa and 100-400 mg of levodopa.

The pharmaceutical composition in dosage form can comprise a sustained release core portion of carbidopa-levodopa overcoated by an immediate release layer of carbidopa-levodopa. The pharmaceutical composition in the dosage form can comprise a multilayer tablet of at least one layer of sustained release carbidopa-levodopa adjacent to at least one layer of immediate release carbidopa-levodopa.

RECEIVED

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE JUN 06 2002

TECH CENTER 1600/2900

In re Application of Alan A. RUBIN

Group Art Unit: 1615

Application No. 08/835,482

Examiner: Seidleck

Filed: April 8, 1997

For: IMPROVEMENT IN TREATMENT OF  
PARKINSON'S DISEASE AND RELATED  
FORMUALTIONS OF THE COMBINATION  
CARBIDOPA-LEVEODOPA

**DECLARATION IN SUPPORT OF PETITION TO REVIVE**

Commission of Patents and Trademarks  
Washington, DC 20231

Dear Sir:

Now comes Alan A. Rubin, the applicant herein, and declares as follows:

1. I am the named inventor for the captioned application;
2. I have had and still have no intent to abandon the inventions of this application or the present application both before May 2002 and all dates subsequent;
3. I learned only in May 2002 that my application was abandoned;
4. I hereby revoke all prior powers of attorney and request that all further mail from the United States Patent and Trademark Office be directed to the following:

Kendrew H. Colton  
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Washington, DC 20006-1201

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EXHIBIT  
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- v) it was developed by employees or agents of POTENTIAL LICENSOR independently of and without reference to any Impax Information or other information that Impax has disclosed in confidence to any third party; or when it is communicated by Impax to a third party free of any obligation of confidence.

5. POTENTIAL LICENSOR agrees that any disclosure of Impax Information after the obligations of Paragraphs 2 and 3 hereof shall have terminated shall not identify Impax as the source of such Information.

6. All materials including, without limitation, documents, drawings, models, apparatus, sketches, designs, and lists furnished to POTENTIAL LICENSOR by Impax and which contain Impax Information shall remain the property of Impax and shall be returned to Impax promptly at its request with all copies made thereof.

7. Communications from POTENTIAL LICENSOR to personnel and authorized representatives of Impax shall not be in violation of the proprietary rights of any third party and shall be made without any obligation of confidence.

8. This Agreement shall govern all communications between Impax and POTENTIAL LICENSOR that are made during the period from May 1, 2002, to the date on which either party receives from the other written notice that subsequent communications shall not be so governed.

9. POTENTIAL LICENSOR shall not export, directly or indirectly, any technical data acquired from Impax under this Agreement or any products utilizing any such data to any country for which the U.S. Government or any agency thereof at the time of export requires an export license or other Government approval without first obtaining such license or approval.

10. This Agreement shall be construed in accordance with the laws of the State of California.

IMPAX CORPORATION

By \_\_\_\_\_

Title:      Date:

POTENTIAL LICENSOR

By: Alan A. Rubin

Dr. Alan A. Rubin

Date: May 24, 2002